K103652
p1/2

JAN 13 2011

510K Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807-92(c).

1. The submitter of this pre-market notification is:

Larry Milana
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810
United States

Tel: 978-659-7860
Fax: 978-659-3819
Email: larry.milana@philips.com

This summary was prepared on December 10, 2010.

2. The names of the subject devices are the Philips SureSigns Series Patient Monitors, SureSigns VM4, VM6, and VM8 Patient Monitors

3. The trade names of the devices are the SureSigns VM4, SureSigns VM6, SureSigns VM8 Patient Monitors.

4. The common usual name is multi-parameter patient monitor

5. The Classification names are as follows:

Device Panel	Classification	ProCode	Description	Applicable Subject Devices
Circulatory System Devices	870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)	VM4, VM6, VM8
	870.1110, II	DSJ	Alarm, Blood Pressure	VM4, VM6, VM8
	870.1110, II	DSK	Computer, Blood Pressure	VM4, VM6, VM8
	870.1130, II	DXN	System, Measurement, Blood Pressure, Non-Invasive	VM4, VM6, VM8
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm	VM4, VM6, VM8
	870.2700, II	DQA	Oximeter	VM4, VM6, VM8
	870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient connector	VM4, VM6, VM8
General Hospital and Personal Use	880.2910, II	FLL	Thermometer, Electronic, Clinical	VM4
Anesthesiology & Respiratory Therapy	868.1400, II	CCK	Analyzer, Gas,	VM8

6. The modified devices are substantially equivalent to previously cleared Philips device, SureSigns VM Series Patient Monitors marketed pursuant to K052707, K080495, K090483, and K101067.

7. The modifications are as follows:

   - The alarm limit range for the Heart Rate (HR) sourced from the ECG, the SP02, or the NBP measurement has been modified to allow for separate ranges for each source. This modification allows the device to offer a wider heart rate (pulse) measurement range for the ECG and SP02 sources while keeping the existing NBP range.

   - Modification of the current Indications for Use to include a list of the measurements the device can perform. The Indications for Use will now read as follows:

     Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

     Standard and optional parameters include:

     •ECG
     •Respiration
     •NBP
     •SpO2
     •IBP
     •CO2
     •Temperature

8. The subject devices have the same Intended Use as the legally marketed predicate device.:

   "The SureSigns VM Series Patient Monitors are for monitoring, recording and alarming of multiple physiological parameters of adults, pediatrics, and neonates in healthcare environments. Additionally, the monitor is intended for use in transport situations within a healthcare facility",

9. The subject devices have the same fundamental technological characteristics as the legally marketed predicate devices. The subject devices use the same design as the predicate devices. The change to heart rate does not change the fundamental characteristics.

10. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the subject devices with respect to the predicates. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device, the specifications of the subject device and test results showed substantial equivalence. The results demonstrate that the Philips SureSigns VM4, VM6 and VM8 Patient Monitors meet all reliability requirements and performance claims and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 13 2011

Philips Medical Systems
c/o Mr. Lawrence Milana
Regulatory Engineer
3000 Minuteman Road
Andover, MA 01810

Re: K103652
Trade/Device Name: SureSigns VM4, SureSigns VM6, SureSigns VM8
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient (with arrhythmia detection or alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: December 10, 2010
Received: December 14, 2010

Dear Mr. Milana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

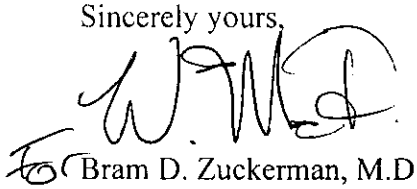
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103652

Indications for Use

JAN 13 2011

510 (k) Number (if known): K103652

Device Name: SureSigns VM4 (reference number: 863063)
SureSigns VM6 (reference numbers: 863064, 863065)
SureSigns VM8 (reference numbers: 863066, 863068)

Indications for Use:

Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

Standard and optional parameters include:

- ECG
- Respiration
- NBP
- SpO2
- IBP
- CO2
- Temperature

Prescription Use: YES AND/OR over-the-counter Use: NO
(Part 21 CFFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103652